

JAN - 4 2001

K002513

510(k) SUMMARY
Astra Tech Implants Dental System
Single Stage Surgery

Submitters Information

Astra Tech, Inc.
430 Bedford Street, Suite 100
Lexington, MA 02173
781-861-7707
Contact: Mr. Niklas Lidskog

Date Prepared

August 12, 2000

Name of Device

Astra Tech Implants - Dental System
Single Stage Surgical Procedure

Classification Name

Endosseous Implant

Predicate Devices

Similar Devices Previously Approved Under K931767 - Astra Tech Implants - Dental System

ITI Dental Implant System – Straumann Institute, LTD approved under K894844, K984104, K983742, K971578, and K955281.

Description of Device and Intended Use

This application provides for revision of the Dental Implant System labeling to allow the alternate use of a single stage surgical protocol for installation of previously approved Astra Tech Implants – Dental System.

The intended use of this device is for selected fully edentulous and partially edentulous arches using one or two stage surgical procedures.

The components are those previously approved to meet various clinical situations in partially and totally edentulous patients. All implants are root-form uncoated screws and are made from commercially pure titanium. The indications and uses for the components are not different from similar components of the predicate device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

JAN - 4 2001

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Niklas Lidskog
President
Astra Tech Incorporated
430 Bedford Street, Suite 100
Lexington, Massachusetts 02420

Re: K002513
Trade Name: Astra Tech Implants - Dental Systems
Regulatory Class: III
Product Code: DZE
Dated: August 14, 2000
Received: August 15, 2000

Dear Mr. Lidskog:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

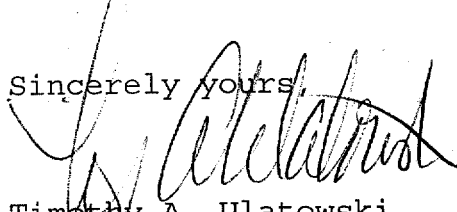
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note:

this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,



Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known):

~~Not Known~~ K002513

Device Name:

Astra Tech Implants – Dental System

Indications for Use:

For use in selected fully edentulous and partially edentulous arches using one or two stage surgical procedures.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Line ✓
(Per 21 CFR 801.1091)

or

Over-The-Counter Use _____

(Optional Format 1-2-9G)

SL Shire DMD for CDRH

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K002513